510(k) Summary for **Analogic Corporation OB-1 Fetal Monitor**

DATE THIS SUMMARY WAS PREPARED: April 27, 2001

SUBMITTER'S NAME AND ADDRESS:

Analogic Corporation 8 Centennial Drive Peabody, MA 01960

CONTACT PERSON:

Steven A. Clarke, Regulatory Affairs Manager

Telephone

(978)977-3000 extension 2388

Facsimile

(978)336-0061

DEVICE NAME:

Proprietary or Trade Name: OB-1 Fetal Monitor

Common Name:

Fetal Monitor

Classification Name:

Perinatal Monitoring System

PREDICATE DEVICE:

The legally marketed device to which equivalence is being claimed is:

FETALGARD Lite Fetal Monitor cleared under Premarket Notification K002503.

DEVICE DESCRIPTION:

The OB-1 Fetal Monitor System consists of the monitor itself, one or two ultrasound transducer(s), tocotonometer, a separate power supply, and optional chart recorder.

Uterine contractions are monitored using an external tocotonometer.

Fetal heart rate is measured using an external pulsed Doppler ultrasound transducer.

Heart rate, and uterine activity are presented graphically on an LCD display or chart recorder.

INTENDED USE:

The OB-1 Fetal Monitor is a Perinatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and optionally on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices and in the patient's home.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

This submission is for modifications to the FETALGARD Lite Fetal Monitor that was cleared for marketing under Premarket Notification K002503. The OB-1 Fetal Monitor is a modification the predicate device which does not change the intended use or the fundamental scientific technology.

The monitor hardware has been modified to work with different transducers, and to support printing to a standard PC printer.

The monitor software has been modified to add support for printing to a PC printer, different protocols for serial data output, and additional foreign language support.

The recorder has been modified to use a parallel data port instead of a serial data port.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

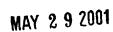
The new device has undergone verification and validation test scenarios to show that all functions are in compliance with the user requirements, safety standards, and performance specifications. This involved the use of both simulated input signals and tape recordings of actual physiological waveforms.

The system has been tested for electrical safety according to IEC 60601-1 and electromagnetic compatibility according to IEC 60601-1-2. The Ultrasound Transducer was tested according to the information requested in the FDA

Guidance Document Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, September 1997.

CONCLUSIONS FROM NONCLINICAL TESTING:

The testing of the OB-1 Fetal Monitor demonstrates the performance is substantially equivalent to the predicate device.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Steven A. Clarke Regulatory Affairs Manager Analogic® Corporation 360 Audubon Road WAKEFIELD MA 01880 Re: K011304

Agilent OB-1 Fetal Monitor Dated: April 27, 2001 Received: April 30, 2001 Regulatory Class: II

21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Clarke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal, and Radiological Devices

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Office of Device Evaluation

Center for Devices and Radiological Health

510(k) Number (if known): K01/304

Device Name: OB-1 Fetal Monitor

Indications For Use:

The OB-1 Fetal Monitor is a Perinatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and optionally on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices and in the patient's home.

(PLEASE DO NOT WI	RITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)
Concur	rence of CDRH, Office of Device Evaluation (ODE)
Prescription Use(Per 21 CFR 801.109)	OR Over-The-Counter Use
	31. Charles
	(Division Sign Off)
	Division of Reproductive, Abdominal, ENT,
	and Radiological Devices 510/b) Number 70/1304
	510(k) Number